Original Investigation Reports

Results of subintimal and intraluminal angioplasty in chronic total occlusion of the superficial femoral artery.

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ABSTRACT

Introduction: endovascular revascularization is key in the management of chronic lower limb ischemia.

Objective: to describe the outcomes of subintimal angioplasty in the treatment of superficial femoral artery chronic total occlusion.

Materials and methods: observational, descriptive, cross-sectional, and prospective study. The study population consisted of patients diagnosed with chronic total occlusion of the superficial femoral artery, treated at a referral center in the Autonomous City of Buenos Aires during the period from January 2022 to December 2023.

Results: 42 patients were selected, median age 68 years, 16 women (38.1%), with a Leriche-Fontaine stage III in 32 patients (76.2%), and IV in 10 (23.8%), and an occlusion length of more than 10 cm in the entire sample. Pre-procedure ABI was less than 0.9 in all cases, and greater than 0.9 post-procedure ($p<.001$). Intra-procedural adverse events occurred in 28 patients (66.7%) and only three required reinterventions.

Conclusion: subintimal and intraluminal angioplasty represent viable and effective revascularization techniques in the treatment of patients with chronic lower limb ischemia in the femoral artery territory.

INTRODUCTION

Critical limb ischemia (CLI) constitutes the most advanced stage of peripheral artery disease, characterized by severe arterial obstruction in the lower limbs, with a high impact on quality of life and a high rate of morbimortality.[1] This scenario, characterized by pain in rest and ischemic lesions, represents a therapeutic challenge. Coronary chronic total occlusions (CTO) are defined as those with ischemic pain in rest (type III of the Leriche-Fontaine classification) or critical ischemia with development of ulcers or gangrene (type IV).[2] CTOs are usually found in CLI, with a frequency of up to 40% in patients with symptomatic peripheral arterial disease. The complex nature of CTOs, particularly those with long lesions and intense calcification, may negatively affect immediate results and the mid-term after endovascular treatment.

Angioplasty or endovascular revascularization has emerged as a safe and efficient alternative, standing out for being less invasive and risky in comparison with open vascular surgery.[3] However, CLI is often associated with diseases in multiple levels of severe calcification, demanding a combined strategy approaching both inflow (aortoiliac and femoral) and outflow (tibial).[4] Although a large part of evidence on the endovascular treatment of inflow comes from studies focused on claudication, specific results in patients with CLI are limited.[1] Angioplasty, that could be made endoluminally or by percutaneous intentional extraluminal recanalization (PIER), offers a viable option, but results in the long term in this population are uncertain.[5,6] This study attempts to describe the results of angioplasty in the treatment of CTO in the superficial femoral artery.

MATERIALS AND METHODS

Design of the study

Observational, descriptive, cross-sectional and prospective study. Its design adhered to the STrengthening the Reporting of Observational studies in Epidemiology (STROBE) recommendations.[7] The study population was made up by patients diagnosed with chronic total occlusion of the superficial femoral artery, who received care in a reference center in the Autonomous City of Buenos Aires, during the term from January 2022 to December 2023.

Selection criteria

All patients older than 18 years, with diagnosis of CLI, with pre-procedure CTO (type III or IV according to the Leriche – Fontaine scale), intervened by angioplasty.[2] Patients with non-atherosclerotic occlusion (thrombosis, dissection or embolism) were not considered in this study. Also, patients in whose clinical files there was no information necessary for this study were excluded.

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FIGURE 1.
Lower limbs arteriography.
3A. Chronic occlusion of the left superficial femoral artery with abundant calcification. **3B.** Endovascular treatment with peripheral rotational atherectomy devices, with aspiration system and self-expandable blades. **3C.** Final outcome with peripheral prosthesis, with appropriate flow and diameter.

Procedure and technique

Anterograde puncture was made with hydrophilic wire 0.35, supported through vertebral catheter of 4 or 5 Fr. Once the wire could be advanced, the catheter was pushed through. Devices for peripheral rotational atherectomy were used, with aspiration system and self-expandable blades *(Figure 1)*. Confirmation was made by angiography. About catheter placements, a wire was placed, through which the balloon or prosthesis was pulled.[8]

Outcomes in the short and long term

Outcomes in the short term constituted the rate of technical and clinical success, and adverse events related with the procedure. Clinical success was defined as the identification of a femoral artery with adequate flow and improvement in ankle-brachial index (ABI). Outcomes in the long term constituted permeability six months after the procedure, and rate of reintervention.

Statistical analysis

Continuous variables are expressed as mean and standard deviation (SD) or median (interquartile range - IQR), according to normal or asymmetrical distribution of data, which was evaluated by the Kolmogorov-Smirnov test. Categorical variables are presented as numbers and percentages.

ABI was contrasted before and after the procedure by Wilcoxon test, and illustrated by alluvial diagram. Work was carried out with a 95% confidence interval, a critical or rejection (alpha) region of 0.05 was preset, associated to the p or probability value. The statistical program SPSS version 25 was used for data analysis.

Ethical and legal aspects

The investigators participating in this study have followed the applicable ethical and legal regulations, namely the Declaration of Helsinki. Informed consent has been obtained from patients, the Committee of Ethics of the hospital has granted its approval.

RESULTS

From a total of 42 selected patients, the median of age was 68 years (IQR 65-72) and 16 were female (38.1%). In regard to comorbidities, 33 had diabetes mellitus (78.6%), 29 hypertension (69%) and 26 dyslipidemia (61.9%) *(Table 1)*. Grade III from the Leriche-Fontaine scale was estimated in 32 patients (76.2%) and grade IV in 10 (23.8%). The length of occlusion was more than 10 cm in the whole sample, with a median of 13 cm (IQR 10-15). A high content of calcium was identified in 31 patients (73.8%), while pre-procedure ABI was less than 0.9 in all cases *(Table 1)*.

The subintimal technique was applied in 33 patients (78.6%) and the endoluminal one in 9 (21.4%), requiring the placement of an endoluminal prosthesis in 33 (78.6%). After angioplasty, all cases presented ABI of 0.9 to 1.0 ($p<.001$). From the 28/42 patients with ABI of less than 1.0 (66.7%), 4/28 presented pre-procedure ABI of 0.5, 0.6 in 9/28, 0.7 in 14/28, and 0.8 in 1/28. From the 14/42 patients with post-procedure ABI of 0.9 (33.3%), 6/14 presented pre-procedure ABI of 0.5, 0.6 in 6/14, 0.7 in 1/14, and 0.8 in 1/14 *(Figure 2)*.

TABLE 1.
Baseline characteristics of the study sample

	(N=42)
Age (years), median (IQR)	68 (65 – 72)
Sex (female), n (%)	16 (38.1)
Diabetes mellitus, n (%)	33 (78.6)
Hypertension, n (%)	29 (69.0)
Dyslipidemia, n (%)	26 (61.9)
Smoking, n (%)	33 (78.6)
Pre-procedure occlusion (Leriche – Fontaine scale), n (%)	
Grade III	32 (76.2)
Grade IV	10 (23.8)
Length of occlusion (cm), median (IQR)	13 (10 – 15)
High calcium content	31 (73.8)
Pre-procedure ABI, n (%)	
0.5	10 (23.8)
0.6	15 (35.7)
0.7	15 (35.7)
0.8	2 (4.8)

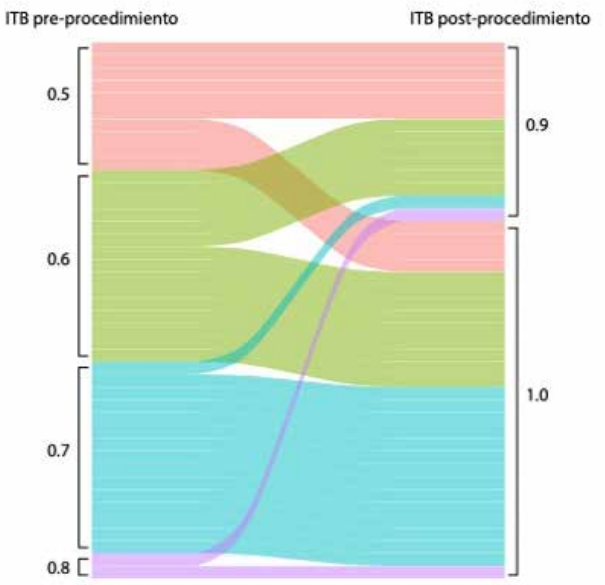

FIGURE 2.
Evolution of the lesions with ischemic origin

TABLE 2.
Percutaneous management, outcomes in the short and long term

	(N=42)
Technique, n (%)	
Endoluminal	9 (21.4)
Subintimal	33 (78.6)
Use of prosthesis, n (%)	26 (61.9)
Post-procedure ABI, n (%)	
0.9	14 (33.3)
1.0	28 (66.7)
Intra-procedure complications, n (%)	
Dissection	8/28
Recoil	20/28
Local hematomas, n (%)	8 (19.0)
Permeability six months after the procedure, n n (%)	40 (95.2)
Vascular reintervention, n (%)	3 (7.1)

Intraprocedure adverse events were documented in 28 patients (66.7%), being dissections in 8/28 patients, and recoils in 20/28. Likewise, local hematomas were documented in eight patients (19%), but no retroperitoneal hematoma. In 40 patients, permeability was shown six months after the procedure (95.2%) *(Figure 3)*. Only in three patients reintervention was necessary, including two in whom there was permeability (7.1%) *(Table 2)*.

DISCUSSION

The first attempt of subintimal angioplasty was in 1987 to treat CTO in the femoral-popliteal segment, with rates of technical success of 76%, and an acceptable rate of complications of 5.6%.[9] In general, the procedure uses the wire and catheter technique to approach the subintimal plane, right above the level of the CTO.[5] A wire forming a loop is used to go through the occlusion in this subintimal space of low resistance, to return to the true lumen of the artery beyond the occlusion. In a systematic review of 23 cohort studies, including 1549 patients with CLI who underwent subintimal angioplasty of peripheral arterial occlusive disease, the reported rates of success and the rates of saving a limb within a year ranged between 80% and 90%. The study concluded that subintimal angioplasty has an important role, particularly in patients with chronic ischemia, to provide wound healing and saving limbs.[10]

A recent Egyptian study compared angioplasty in 260 patients treated at the level of the superficial femoral artery vs 190 treated at the level of the popliteal artery, reporting a global technical success in 93.3% of cases. Lesions at the level of the superficial femoral artery presented a technical success of 91.2%. The prevalence of vessels of null leakage in patients treated at the level of the superficial femoral artery was 11.5%, contributing to a better rate of technical success. Nevertheless, technical success in literature can reach up to 95.1% for the treatment with subintimal angioplasty of CTO at femoral-popliteal level.[11]

In the case of patients with CLI that present severe symptoms and that also present a prohibitive surgical risk, a deficient drainage, and lack of a proper autologous duct, many medical societies consider that angioplasty is the first line therapy, in spite of the anatomical limitation of the disease.[12,13] However, conventional femoral access during angioplasty of complex arterial lesions

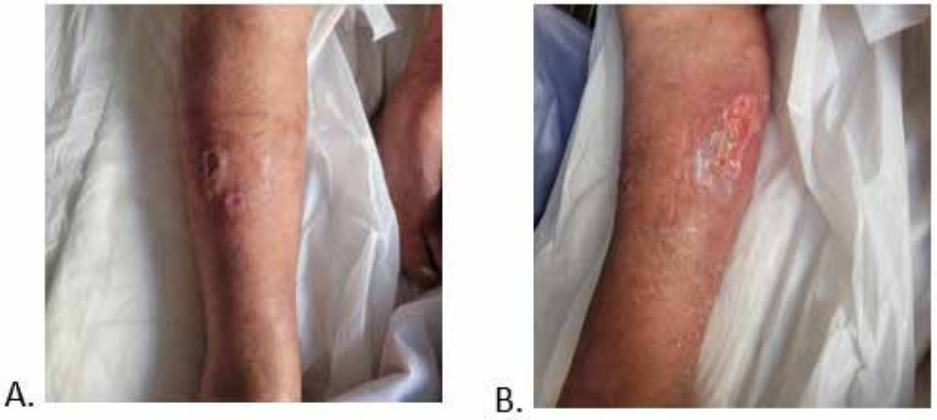

FIGURE 3.
Evolution of the lesions with ischemic origin

could be very complicated, and may fail in up to 20% of cases.[14] Furthermore, there are different preferences in regard to the anterograde vs retrograde approach, with the anterograde being the one most commonly used. However, one of the advantages attributed to using retrograde access is a softer distal occlusion cap in comparison with the hard fibrotic proximal cap, through which the retrograde wire can pass more easily. It also provides a greater capacity for the wire to be pushed due to the closeness of the CTO with the retrograde access, together with a lower possibility for the retrograde wire to shift toward the lateral branches that originate in a craniocaudal direction.

It is important to highlight that a selective placement of the endoluminal prostheses is more frequent in lesions at superficial femoral level vs popliteal level. Unlike the superficial femoral artery approach, the popliteal artery has a different embryology, as it originates at the sciatic system. Furthermore, while the superficial femoral artery and the tibial artery have an intramuscular course, the popliteal artery does not go through any muscle compartment. Even more important, the popliteal artery is exposed to huge biomechanical forces due to the frequent flexion of the knee and the repetitive movement of the ankle. These distinctive properties of the popliteal artery may affect the results of the endovascular treatment options.[15] Consequently, the acceptable concerns about vessel kinking and a possible restenosis and prosthesis fractures lead to consider that this vessel is not appropriate for prosthesis placement.

The ideal result from revascularization in patients with peripheral arterial disease is the complete relief of ischemic symptoms, particularly wound scarring in patients with ischemic wounds. Therefore, the evaluation of these patients should consider wound scarring and maintenance of a state free from wounds.[16] The scarring rates of wounds are significantly better in the superficial femoral artery approach within three months (more than 30%) and in one year (more than 80%).[17] Even with moderate permeability rates in the long term, one of the valuable results of subintimal angioplasty in patients with CLI is helping to wound scarring and recovering the limb, as supported by an extensive systematic review.[12]

This study presents certain limitations. It was a retrospective, single-center study, with one arm, focused on the management of superficial femoral artery. The number of cases prevented making some specific subgroups analyses. A future aim is performing a large prospective multicenter study, thoroughly comparing subintimal angioplasty of CTO using different types of prosthesis, as well as the results from subintimal angioplasty versus intraluminal angioplasty.

CONCLUSIONS

Subintimal and endoluminal angioplasty represent feasible and efficient revascularization techniques in the treatment of patients with CLI of the CTO type at the level of the superficial femoral artery. A high rate of revascularization is achieved with a low rate of reintervention. These techniques should be considered a first line treatment in patients with such a process, saving surgical revascularization for individuals in whom the percutaneous procedure has failed.

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